



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/800,296

03/12/2004

Dmitry Bulavin

225694

9189

45733

7590

08/16/2006

LEYDIG, VOIT & MAYER, LTD.  
TWO PRUDENTIAL PLAZA, SUITE 4900  
180 NORTH STETSON AVENUE  
CHICAGO, IL 60601-6780

EXAMINER

FETTEROLF, BRANDON J

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/800,296

Applicant(s)

BULAVIN ET AL.

Examiner

Brandon J. Fetterolf, PhD

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 18, 21, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 19, 20 and 22-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

The Election filed on June 7, 2006 in response to the Restriction Requirement of April 7, 2006 has been entered. Applicant's election of Group II, claims 17-23, as specifically drawn to a pharmaceutical composition comprising any one of compounds A-N has been acknowledged. Applicants have further elected Compound H as the single disclosed invention for prosecution on the merits.

Applicant's election of Group II with traverse is acknowledged and has been entered. The traversal is on the grounds that there are two separate criteria for a proper requirement for restriction between patentably distinct inventions: (i) the invention must be independent or distinct as claimed and (ii) there must be a serious burden on the Examiner if restriction is not required. In view of this, Applicants assert that the fact a patentability search for one group of claims may not be completely "coextensive" with the patentability search for another group of claims, as the Office Action alleges, does not necessarily mean that conducting such searches concurrently would place a "serious burden" on the Examiner. Applicants further argue that since all of the pending claims relate to compound that inhibit WIP-1 or methods for the use of such compounds, there would be no absence of such a "serious burden" on the Examiner to address all of the pending claims at one time. In the absence of such a "serious burden," the restriction requirement is improper even if groups of claims are drawn to distinct inventions.

These arguments have been carefully considered, but are not found persuasive.

As to the question of burden of search, the inventions are classified differently, necessitating different searches of the US Patents. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. Different searches and issues are involved in the examination of each group. For example, the compounds of Group II may be characterized in the technical literature prior to the discovery on how to use the compounds of Group II. Moreover, the methods of Groups I and III are patentably distinct because the methods are divergent in materials and steps.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Art Unit: 1642

After careful review and reconsideration, the Examiner has rejoined Compound M for prosecution on the merits due to its close structural similarity to Compound H.

Claims 1-25 are currently pending.

Claims 1-16, 18, 21 and 24-25 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 17, 19-20 and 22-23 are currently under consideration.

### ***Priority***

The instant application is a continuation in part of PCT/US03/08997 filed on 03/21/2003, which claims benefit of 60/366,833 filed on 03/22/2002. After reviewing PCT/US03/08997 for the disclosure of Compound H and Compound M, the Examiner has established a priority date of **March 12, 2004 (Serial Number 10/800,296)**. If applicant disagrees with any rejection of claims 17, 19-20 and 22-23 set forth in this office action based on examiner's establishment of a priority date of **March 12, 2004** for the instant claims in application serial number 10/800,296 applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

### ***Information Disclosure Statement***

The Information Disclosure Statements filed on 3/12/2004 and 12/21/2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

### ***Specification***

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see for example, page 11 paragraph 0033. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

### ***Claim Objections***

Claims 17, 20 and 23 are objected to because of the following informalities:

Claims 17, 20 and 23 are objected to for reciting non-elected compounds in addition to Compound H and M, which Applicants elected as the single disclosed invention for prosecution on the merits.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17, 19-20 and 22-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Benz (WO 03/035,843 A2, priority date of 10/25/2001, *IDS*).

Benz teaches a histone deacetylase inhibitor referred to NSC-321237, which appears to be identical to Compound M claimed in the instant application (page 5, paragraph 0017 and Figure 6). The WO document further teaches pharmaceutical composition comprising the histone deacetylase inhibitors, wherein the histone deacetylase inhibitors are combined with a pharmaceutically acceptable carrier (page 29, paragraph 0103).

Claims 17, 20 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Sinclair (US 2005/0096256, 2003).

Sinclair discloses an inhibitor of sirtuins referred to as Mercury, (2-hydroxy-5-nitrophenyl)(6-thioguanosinato-N7, S6) which appears to be identical to Compound H claimed in the instant application (page 44, paragraph 0997, Reg# 745811-54-5). The publication further teaches a

Art Unit: 1642

pharmaceutical composition comprising the sirtuin inhibitors, wherein the sirtuin inhibitors are combined with a pharmaceutically acceptable carrier (page 56, beginning with paragraph 1148).

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD  
Patent Examiner  
Art Unit 1642

BF

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER